



Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

June 26, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, D.C. 20460

Re: Request to Withdraw and Correct the 2010 IRIS Review of Chloroprene

Dear Administrator Pruitt:

I write on behalf of Denka Performance Elastomer LLC (DPE) in support of the request that the U.S. Environmental Protection Agency (EPA) withdraw and correct its Integrated Risk Information System (IRIS) Toxicological Review of Chloroprene (EPA/635/R-09/010F, 2010) (the 2010 IRIS Review). The errors in the 2010 IRIS Review threaten the very survival of DPE's Neoprene production facility in LaPlace, Louisiana (Facility). In particular, based on those errors and EPA's subsequent flawed determinations concerning the risks caused by Facility emissions, EPA is making stringent air pollution control demands concerning the Facility that are technologically impossible to achieve. EPA must expeditiously apply good science in this matter in order to alleviate the public's undue concerns about the risks associated with this Facility and to prevent further significant damage to DPE's business.

Key conclusions of the 2010 IRIS Review are not based on the best available science or sound scientific practices. First, the 2010 IRIS Review rejected the findings of the strongest available epidemiological study, which concluded that there is no increased risk of cancer in workers exposed to chloroprene (some of the study cohorts actually exhibited a *lower* risk of cancer than the control population). Rather than accepting the overall study conclusions, the 2010 IRIS Review relied on select statistically non-significant comparisons of cancer incidence rates among subgroups of the larger epidemiology study to bolster its classification of chloroprene as "likely to be carcinogenic to humans." Second, the 2010 IRIS Review is flawed because it relied on laboratory animal studies, and then used the results for the most sensitive laboratory animal – female mice – as the basis for a series of overly conservative calculations to develop the human inhalation unit risk (IUR). Contrary to sound scientific practice, the 2010 IRIS Review ignored the known differences between humans and a select strain of female laboratory mice, and relied on results in those female mice to estimate an IUR for humans. Third, the 2010 IRIS Review gives chloroprene, which EPA designates only as a "likely" and not a "known" human carcinogen, the fifth highest IUR estimate of any similar chemical, including known human carcinogens, in the IRIS database. DuPont, the former Facility owner, provided similar information and analysis to EPA in comments on the draft IRIS Review, which comments were rejected in 2010. DPE's Request for Correction and the Ramboll Environ report provide new information and weight-of-evidence review not available in 2010.



Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

After EPA published the 2010 IRIS Review, the National Academies of Sciences' National Research Council (NRC) recommended major reforms in the IRIS process. Congress has repeatedly instructed EPA to implement the NRC's recommendations, and EPA has advised Congress that it is doing so. The 2010 IRIS Review is plagued with flaws similar to those that gave rise to these reform initiatives, and it is extremely important that the 2010 IRIS Review now be corrected in light of its scientific and procedural deficiencies.

These issues are more fully explained in DPE's Request for Correction and in the supporting toxicological and epidemiological expert review prepared by prominent scientists with the consulting firm of Ramboll Environ: Drs. Kenneth Mundt, Robinan Gentry, and Sonja Sax. Their report is entitled *Basis for Requesting Correction of the U.S. EPA Toxicological Review of Chloroprene*, dated June 2017 ("the Ramboll Environ Report," and attached hereto). The Ramboll Environ Report identifies multiple substantive errors in the 2010 IRIS Review and demonstrates that if chloroprene is to be treated as a possible human carcinogen, the 2010 IRIS Review establishes an IUR that is 156 times too high.

By way of background, DPE acquired the Neoprene Facility from DuPont on November 1, 2015. Neoprene is a synthetic rubber utilized in a wide variety of applications, including laptop sleeves, orthopedic braces, electrical insulation, and automotive fan belts. DPE is the only manufacturer of Neoprene in the United States. The Facility is a commercial mainstay of LaPlace, Louisiana. With an annual payroll of \$33 million, DPE directly employs 200-250 people in manufacturing jobs and regularly employs between 125 and 150 contractors. DPE also has created 16 new corporate jobs. Additionally, DPE is investing and upgrading the Facility, including taking new measures to reduce its environmental footprint and improve its productivity and competitiveness.

The base feedstock for Neoprene is chloroprene. The Facility's air permits authorize it to emit chloroprene, and the Facility operates in compliance with those permit limits. However, shortly after DPE's acquisition of the Facility, on December 17, 2015, EPA publicly released its 2011 National Air Toxics Assessment (NATA), which identified the Facility as creating the greatest offsite risk of cancer of any manufacturing facility in the United States. The NATA findings concerning the Facility are based on the scientifically unwarranted and outdated 2010 IRIS Review and the emission profile of the Facility.

Following the public release of the NATA, EPA and the Louisiana Department of Environmental Quality (LDEQ) pressed DPE to reduce emissions to achieve an extraordinarily miniscule ambient air target concentration of $0.2 \mu\text{g}/\text{m}^3$ for chloroprene on an annual average basis (which is intended to reflect a 100 in 1,000,000 rate of potential excess cancers in a population exposed to such concentrations continuously for 70 years). The $0.2 \mu\text{g}/\text{m}^3$ target is based on a risk assessment that applied the erroneous and scientifically unsubstantiated IUR from the 2010 IRIS Review, and the target reflects more than a four thousand-fold reduction in the applicable Louisiana 8-hour ambient standard for chloroprene. Ramboll Environ's expert scientific opinion is that the appropriate risk-based ambient target should be 156 times larger or $31.2 \mu\text{g}/\text{m}^3$. There is no agency rule or even proposed rule requiring the attainment of the $0.2 \mu\text{g}/\text{m}^3$ target, yet EPA has advised DPE, LDEQ, and the public that $0.2 \mu\text{g}/\text{m}^3$ is the appropriate target.

As a result of the flawed science embodied in the 2010 IRIS Review, and as a result of the NATA findings and the Facility's emission profile, DPE has suffered extraordinary hardship in a number of ways.



Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

First, despite DPE's concerns about the science behind the 2010 IRIS Review, DPE is currently spending more than \$18 million on new pollution controls. On January 6, 2017, DPE entered into an Administrative Order on Consent with LDEQ to reduce chloroprene emissions by approximately 85% below the level of the Facility's 2014 emissions. DPE estimates that the capital cost of these emission reduction devices is approximately \$18 million, and the devices will cost hundreds of thousands of dollars per year to operate. Even though DPE is installing the most advanced air pollution controls available, it will still not be able to meet the stringent 0.2 $\mu\text{g}/\text{m}^3$ target.

Second, because the 2010 IRIS Review is flawed, EPA's very public announcements arising out of that Review and the NATA have created unnecessary public alarm. For example, after issuing the NATA, EPA created a public webpage specifically addressing DPE's chloroprene emissions.¹ Moreover, environmental activists and plaintiffs' lawyers have had numerous meetings in the community about DPE, all based on the faulty assumption that 0.2 $\mu\text{g}/\text{m}^3$ is the "safe" level for chloroprene. Further, a local citizen's group has formed and has been handing out misleading flyers and protesting near DPE's Facility. The erroneous IUR in the 2010 IRIS Review and the resulting NATA findings have caused DPE enormous reputational damage.

Third, as a result of the NATA findings, EPA Region 6 asked the National Environmental Investigations Center (NEIC) to investigate the regulatory compliance status of the Facility. NEIC sent a team of inspectors to the Facility from June 6-10, 2016, approximately seven months after DPE's acquisition. To be clear, DPE fully respects the important function of the EPA in enforcing environmental requirements. It is simply a fact, however, that as a result of the erroneous IUR and the NATA findings, EPA has initiated an enforcement proceeding against DPE and has devoted an extraordinary amount of resources from the Department of Justice, EPA headquarters, EPA Region 6, and NEIC to developing and pursuing the issues in the NEIC report.

Finally, since acquiring the Facility in November of 2015, DPE's relatively small management team has been buffeted by continuous environmental regulatory demands resulting from the erroneous IUR and the NATA findings. In addition to Facility operation, DPE staff has been in non-stop meetings and negotiations with EPA and LDEQ. DPE's legal and consulting expenses have been enormous, in the millions of dollars. Underlying all of these expenses and burdens on DPE is the erroneous IUR in the 2010 IRIS Review, as applied in the NATA risk assessment.

DPE needs EPA's assistance in the expeditious application of good science to this matter. In meetings with EPA in 2016 concerning the need to correct the 2010 IRIS Review, EPA officials advised DPE that EPA's "queue is full". DPE respectfully requests that EPA review the science underlying the 2010 IRIS Review, withdraw the erroneous IUR, and develop a more accurate toxicological review of chloroprene. We are confident that the Ramboll Environ Report will lead you to these conclusions. Without

¹ See <https://www.epa.gov/la/laplace-louisiana-background-information>.



Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

this relief, it is uncertain whether DPE will be able to reduce emissions sufficiently to satisfy agency demands, or even continue operation.

Sincerely,

A handwritten signature in dark ink, appearing to read "Koki Tabuchi". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Koki Tabuchi
President and Chief Executive Officer
Denka Performance Elastomer LLC